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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/910,033 | 07/23/2001 | Bettina Bommanus | 210212US0X | 2456 |

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| EXAMINER |
| PAK, YONG D |

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| ART UNIT | PAPER NUMBER |
| 1652 | |

DATE MAILED: 05/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,033

Applicant(s)

BOMMANUS ET AL.

Examiner

Yong Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 8-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed February 19, 2003, amending claims 1, 7, 12 and 18, has been entered.

Claims 1-41 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

Election/Restrictions

Claims 8-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Notice of Possible Rejoinder: The Examiner notes that if claims 1-7 are found directed to an allowable product, then claims 12-18, which are directed to the process of making the patentable product, respectively, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also MPEP 821.04, *In re Ochiai*, and *In re Brouwer*). Since process claims 7, 15, and 17 would be rejoined and fully examined for patentability under 37 CFR 1.104, applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hummel et al. (WO 99/47684 – form 1449)

The mutant *Lactobacillus brevis* dehydrogenase of SEQ ID NO:2 of the instant invention differs from the wildtype dehydrogenase by one residue, an Aspartic acid at position 38 instead of a Glycine. Hummel et al. (WO 99/47684) teach a mutant alcohol dehydrogenase from *L. brevis* wherein a Glycine, which corresponds to the residue 38 at position of SEQ ID NO:2 of the instant invention, has been mutated to an Aspartic acid (pages 2-6 and claims 1-12). Hummel et al. teach that the mutant dehydrogenase has greater affinity towards NAD(H) (pages 2-6).

Hummel et al. teaches that alternatively, or additionally, the basicity of amino acids in the coenzyme docking area can be reduced by displacement of **neutral** or positively charged amino acids with **negatively charged amino acids** (abstract and page 2, 2nd paragraph). Therefore, the disclosure of Hummel et al. is not solely drawn to modifying alcohol dehydrogenases by altering only basic amino acids, but also altering neutral amino acids with acidic amino acids or negatively charged amino acids to lower the basicity of the amino acids in the coenzyme docking area. This coenzyme docking area is specifically taught in the disclosure, page 2.

Therefore, the teachings of Hummel et al. anticipate claims 1-7.

Response to Arguments

Applicant's arguments filed February 19, 2003 have been fully considered but they are not persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, without the recitation of the SEQ ID NO, position "38" is unclear. To overcome this rejection, the claim can be amended as "amino acid change at amino acid position 38 of SEQ ID NO:2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 remain rejected under 35 U.S.C. 102(e) as being anticipated by Hummel et al.

Applicants argue that Hummel et al. do not anticipate the present claims because the reference of Hummel et al. describes altering basic amino acids in the coenzyme binding site of alcohol dehydrogenase and therefore the reference is directed to the replacement of primarily basic amino acids in the coenzyme binding site and also that Example 5 is directed to the G37D mutation along with three other mutations.

The examiner disagrees. Hummel et al. teaches that “alternatively, or additionally, the basicity of amino acids in the coenzyme docking area can be reduced by displacement of **neutral** or positively charged amino acids with **negatively charged amino acids**” (Column 1, lines 57-62). Therefore, the disclosure of Hummel et al. is not solely drawn to modifying alcohol dehydrogenases by altering only basic amino acids, but also altering neutral amino acids with acidic amino acids or negatively charged amino acids to lower the basicity of the amino acids in the coenzyme docking area. This coenzyme docking area is specifically taught in the disclosure, Column 2, lines 10-15.

Therefore, in conjunction with claim 2 (Column 29-30), which is also part of the disclosure, which teaches a *Lactobacillus brevis* dehydrogenase wherein at least one neutral amino acid, Glycine, is mutated into an acidic amino acid, Aspartic Acid, wherein the mutant enzyme exhibits an increased affinity towards NAD(H), the reference of Hummel et al. anticipates the instant claims.

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

April 30, 2003



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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